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Information for Healthcare Professionals: Haloperidol (marketed as Haldol, Haldol Decanoate and Haldol Lactate)

[For additional information about this drug, see Haloperidol Information[1].]

FDA ALERT [9/2007]: This Alert highlights revisions to the labeling for haloperidol (marketed as Haldol, Haldol Decanoate and Haldol Lactate). The updated labeling includes WARNINGS stating that Torsades de Pointes and QT prolongation have been observed in patients receiving haloperidol, especially when the drug is administered intravenously or in higher doses than recommended. Haloperidol is not approved for intravenous use.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

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This advisory addresses the risk of QT prolongation and Torsades de Pointes (TdP) in patients treated with haloperidol (a butryphenone antipsychotic), especially when given intravenously.

Recommendations and considerations for healthcare professionals:

Although injectable haloperidol is approved by the FDA only for ***intramuscular injection***, there is considerable evidence from the medical literature that ***intravenous administration*** of haloperidol is a relatively common "off-label" clinical practice, primarily for treatment of severe agitation in intensive care units. Due to a number of case reports of sudden death, TdP and QT prolongation in patients treated with haloperidol (especially when the drug is given intravenously or at doses higher than recommended), the sponsor has updated the labeling for haloperidol. The updated WARNINGS note that:

- Higher doses and intravenous administration of haloperidol appear to be associated with a higher risk of QT prolongation and TdP.

- Although cases of sudden death, TdP and QT prolongation have been reported even in the absence of predisposing factors, particular caution is advised in treating patients using any formulation of haloperidol who:
  - have other QT-prolonging conditions, including electrolyte imbalance (particularly hypokalemia and hypomagnesemia),
  - have underlying cardiac abnormalities, hypothyroidism, or familial long QT syndrome, or
  - are taking drugs known to prolong the QT interval.

EXHIBIT 29

- Because of this risk of TdP and QT prolongation, ECG monitoring is recommended if haloperidol is given intravenously.
- Haloperidol is not approved for intravenous administration.

Clinical Data

There are at least 28 case reports of QT prolongation and TdP in the medical literature, some with fatal outcome in the context of off-label intravenous use of haloperidol. In addition to these cases, case-contro studies have demonstrated a dose-response relationship between intravenous haloperidol dose and subsequent TdP. Based on this information, as well as the biologic plausibility of QT prolongation with intravenous haloperidol, FDA has strengthened warnings in the haloperidol labeling with regard to the risk of TdP and QT prolongation with intravenous haloperidol use.

At the request of the Pharmacovigilance Department of the Italian Drug Agency (AIFA), the sponsor (Johnson & Johnson) performed two post-marketing analyses of QT interval prolongation and TdP with haloperidol administration (oral or injectable). In one analysis, the sponsor searched their Benefit Risk Management worldwide safety database for QT prolongation -related adverse event reports received through June 30, 2005. This search identified 229 reports, many of which the sponsor described as confounded by concomitant QT-prolonging drugs or medical conditions. The reports included 73 cases of TdP, eleven of which were fatal. Eight of the eleven fatal cases involved intravenous administration of various doses of haloperidol.

In March 2007 the sponsor submitted to FDA the results of a second post-marketing investigation conducted for the Italian drug authority[1]. This report examined cardiac adverse events with haloperidol decanoate received by the sponsor as of July 30, 2005. The sponsor found thirteen reports including TdP, QT prolongation, ventricular arrhythmias and/or sudden death.

Based on case reports alone, we are unable to estimate the frequency with which QT prolongation or TdP occur following administration of these drugs.

Next Steps

Healthcare professionals should consider this new risk information when making individual treatment decisions for their patients. FDA will continue to monitor post-marketing reports for QT prolongation and Torsades de Pointes in patients treated with haloperidol, and will analyze any additional data for this as well as other important adverse events. FDA will consider further regulatory action and communication as additional information becomes available.

[1] NDA 20-919 (Haloperidol). QT Prolongation in Association with the Use of Haloperidol Decanoate: a Response to the Pharmacovigilance Department of the Italian Drug Agency. Prepared by Johnson & Johnson Pharmaceutical Research and Development, L.L.C. Dated October 2005.

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